MeD UD – A Process Reference Model for Usability Design in Medical Devices

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Abstract. A critical component to the success of software systems is the incorporation of the end user. Ensuring that the end user can use the system effectively and efficiently is an important consideration. Failure to do this can lead to user error which in turn can have serious or even fatal consequences. To address this issue in the medical domain, where the risk to patient and user safety is quite high, a number of standards and guidance documents promote the use of Human Factors and Usability Engineering techniques during the development of devices. In this paper we introduce MeD UD (Medical Device Usability Design) – A Process Reference Model (PRM) for evaluating usability engineering in the medical device domain. Through a process assessment utilising the MeD UD PRM, medical device organisations can improve their usability design processes to achieve more usable products, reduce the risks associated with user errors and efficiently meet the medical device regulatory requirements.

Keywords: Usability, Medical Device Software, Process Reference Model, IEC 62366:2007

1 Introduction

The development of technology in recent years has allowed for medical devices to provide more effective and efficient patient care. These results can be attributed, in part, to the increasing role of software within medical devices. Through the use of software, complex configuration changes can be implemented easily. In 2006, it was noted that software was now incorporated into over half of the medical devices for sale on the U.S. market [1].

A side effect of the increased complexity of medical devices is the increased chance of human-error. Errors, slips and lapses can occur in every aspect of human activity. When these mistakes occur with medical devices the results can be fatal. In 2007, Ms. Myra Jean Garman took her own life to escape the pain she suffered as a result of the misapplication of a medical device. Ms. Garman, who was suffering from breast cancer, was left in severe pain after she was given twice the recommended dose of radioactive seeds on five separate occasions. The state regulators attributed the over radiation to a mistake on behalf of a physicist who had entered an incorrect mag-

adfa, p. 1, 2011.

nification factor into the treatment planning computer. [2] Ms. Garman is unfortunately not an isolated incident. In New Jersey 36 cancer patients were over-radiated and a further 20 received substandard treatment due to human-error during the application of a medical device [2].

Errors like these can be reduced through the use of usability engineering. Usability engineering is the "*application of knowledge about human behaviour, abilities, limitations, and other characteristics related to the design of tools, devices, systems, tasks, jobs, and environments to achieve adequate usability*" [3]. The incorporation of human aspects into the design process enables designers to develop interfaces in accordance with the users' expectations and needs which can improve the overall user experience and reduce the likelihood of human error.

Software Process Improvement (SPI) frameworks such as SPICE [4] or CMMI [5] allow organisations to improve their software development processes. These models divide the software development process into a number of discrete processes and outline the objectives to be achieved when undertaking these processes. Through an SPI assessment an organisation's weaknesses and strengths can be identified and guidance can be provided as to how they can improve their existing processes.

To assist organisations improve their usability design processes, this work outlines the MeD UD (Medical Device Usability Design) framework which has been developed specifically for the medical device domain. This framework incorporates the latest thinking from the IEC 62366:2007 [3] standard, and the US Food and Drug Administration (FDA)'s *Applying human factors and usability engineering to optimise medical device design* [6] on the topic of usability and human factors engineering.

The remainder of this paper is structured as follows: Section 2 provides the background to this work. Section 3 discusses software process improvement within the medical device domain. Section 4 describes the research methodology used during the development of MeD UD while Section 5 outlines the MeD UD framework. Section 6 discusses how the MeD UD framework is different from existing usability assessment models. Section 7 then discusses the future of this work before the paper is concluded in Section 8.

2 Background and Related Work

2.1 The Role of Software in Medical Devices

Software is omnipresent, affecting every aspect of our daily lives. It is incorporated in most household devices, including items as diverse as washing machines and DVD players, in motor vehicles, and even in wrist watches. It is no surprise therefore that medical devices are becoming more dependent on software. In 2006, Faris [1] found that software was incorporated in over 50% of medical devices for sale in the United States of America.

The choice for using software in medical devices is motivated by the ease with which it can allow complex changes to be made, without the need for expensive hardware changes. However the use of software brings with it a number of risks. In

the first half of 2010 the FDA recalled 23 medical devices which were classified as Class I, meaning that there is "*reasonable probability that use of these products will cause serious adverse health consequences or death*". It was found that of these recalls 6 were likely to be caused by software defects [7].

Also in 2010 the FDA published a white paper [8] detailing an improvement initiative which they undertook to improve the quality of infusion pumps. This initiative arose out of concerns due to the quality of infusion pumps being sold in the US. Between 2005 and 2009 the FDA received approximately 56,000 reports of adverse events associated with the use of infusion pumps, including numerous injuries and deaths. During this same period 87 infusion pumps were recalled, 14 of which were designated as Class I and 70 were designated as Class II, meaning that the use of the device may cause temporary or medically reversible adverse consequences or that the probability of serious adverse health consequences or death is remote.

Many of these adverse events are related to deficiencies in device design and engineering. Although the range of potential issues is quite large, in the report the FDA outline three of the most common types of problems reported, namely software defects, user interface errors and mechanical or electrical failures.

In 2007 the European Council amended the Medical Device Directive (MDD) [9], which governs the approval and marketing of medical devices in the European Union (EU). This amendment came into effect in March of 2010. As part of this amendment the EU recognized the importance of software and revised the directive to include the provision that software can now, in its own right, be classified as a medical device. As a result software can now be subjected to the same regulations and standards as other medical devices [10].

2.2 Medical Device Regulations, Standards and Guidance Documents

In order to sell a medical device within the European Union (EU), the medical device organisation must demonstrate that they are compliant with the regulations set forth by the EU. Similarly, to sell medical devices within the US the organisation must demonstrate compliance with the FDA regulations [11]. In order to help organisations achieve compliance with these regulations the EU and FDA have published guidance documents that address specific aspects of the regulations and also recommend compliance with harmonised and consensus international standards. Medical device organisations may chose not to follow these guidelines and standards and still receive approval to market their device; however they must provide strong justification for not doing so.

One of the most fundamental requirements of a medical device organisation to achieve regulatory compliance is the implementation of a Quality Management System (QMS). A QMS ensures that the processes used during the development and production of a medical device are defined and monitored to ensure high quality products are developed. The requirements of a quality management system have been outlined by the International Organisation for Standardization (ISO) in ISO 13485:2003 [12]. This standard is referred to by the European regulations and has recently been accepted by the FDA as adequate fulfilment of the requirements of a QMS.

As part of the QMS, organisations must perform risk management activities. To improve the quality of the medical devices, the organisation should identify all risks possible and take appropriate action to help mitigate these risks. ISO 14971:2007 [13] describes the requirements of a risk management process for medical device development. This standard identifies 6 key stages; risk analysis, risk evaluation, risk control, evaluation of overall residual risk acceptability, risk management report, and production and post-production information.

IEC 62304:2006 – *Medical device software – Software life cycle processes* [14] provides specific guidance on how to perform software development activities for software that is to be incorporated in a medical device. This is an EU harmonised standard and is recognised by the FDA as a consensus standard. It is therefore used to develop medical device software for both the European and US markets.

2.3 Usability

The ISO [15] define usability as "*The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.*" In this definition, the ISO identify three factors that should be considered when designing usable products; **user**, **goals** and **context of use**. A deep understanding of each of these factors is essential for the development of a usable application as they can all affect the way in which it is used.

- **User: -** refers to the person that will interact with the application. By understanding the user of the system application designers can avoid a number of issues that can make a system difficult to use. For example, consider the development of a mobile application for the management of diabetes. Diabetic patients can suffer from retinopathy which limits the patients' vision thus making it difficult to see. During the design of a mobile application for diabetic patients knowledge of this may encourage developers to increase the size of fonts and objects displayed.

- **Goals: -** refers to the intended outcome of the user. An understanding of the task to be completed can be critical to the success or failure of a product. During the development of a new application the designer must understand what the user is trying to accomplish as well as why they are doing it in such a way. In some cases it can be found that application designers are restricted in the improvements they can make by regulations.

- **Context of use**: - refers to the location in which the application is to be used. This can include the physical and social elements of the environment in which the application is to be used. The environment can limit the methods of input and output putting extra constraints on the developer. For example medical devices that are to be used in a noisy environment should contain alarms that can alert the user through the background noise, either through the use of a flashing light or a loud alarm.

The ISO definition also outlines three measurable attributes that reflect the overall usability of the application:

- **Effectiveness**: Accuracy and completeness with which users achieve specified goals;
- **Efficiency**: Resources expended in relation to the accuracy and completeness with which users achieve goals;
- **Satisfaction**: Freedom from discomfort, and positive attitudes towards the use of the product.

A number of other models of usability have been proposed over the years. One of the most widely acknowledged was originally proposed by Nielsen [16]. In his model, Nielsen outlines five attributes of usability that should be considered:

- **Efficiency**: Resources expended in relation to the accuracy and completeness with which users achieve goals;
- **Satisfaction**: Freedom from discomfort, and positive attitudes towards the use of the product.
- **Learnability**: The system should be easy to learn so that the user can rapidly start getting work done with the system;
- **Memorability**: The system should be easy to remember so that the casual user is able to return to the system after some period of not having used it without having to learn everything all over again;
- **Errors**: The system should have a low error rate, so that users make few errors during the use of the system and that if they do make errors they can easily recover from them. Further, catastrophic errors must not occur.

Unlike the ISO, Nielsen does not consider effectiveness to be an attribute of usability, but instead an attribute of utility. In this model, Nielsen considers utility to be the ability of the system to allow the user to accomplish their task and is independent of usability.

There are a number of techniques that can help application developers to develop usable products, such as user centred design. User centred design focuses on the needs, demands and requirements of the end user. Holzinger et al. [17] outlines one such process that has been proven on many projects.

The protocol outlined in Fig. 1, adopted from [18], shows how user centred design can be performed, highlighting the role of the user throughout the development of the medical device. The process begins with the identification of end-users who are represented throughout the rest of the process. To aid in the development of a usable system, after analysis the processes recommends the development of low-fidelity prototypes that are tested with real users to determine which approaches work best. After this a high-fidelity prototype is developed which provides a rich user experience for the user to evaluate. The process then recommends development, once a suitable design has been found. This is then tested further to ensure it is usable before it is released.

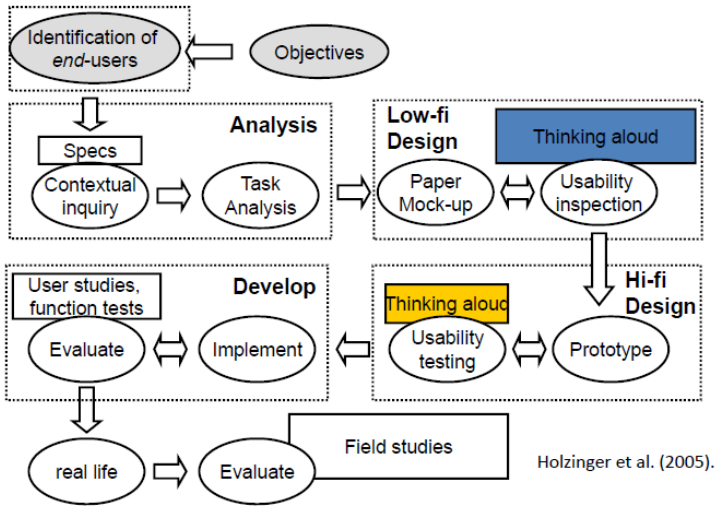

Fig.1. A Method for User Centred Design

This approach makes extensive use of the Think Aloud protocol, which allows analysts to understand how users approach a task by requiring them to describe what they are thinking while completing the task. This approach helps to reduce the costs as think aloud is a low cost method that can be applied throughout the development process from analysis to test.

2.4 The Usability of Medical Devices

Compliance with the standards outlined above can help to prevent software from failing through the elimination of software defects. Conformance with these regulations and standards do not provide protection against human error. More than 300 patients were over radiated by powerful CT scanners, which had obtained FDA approval, used to detect strokes in four hospitals in the US. In one hospital, which detected the errors after 18 months when patients started losing their hair, found that the overdose was displayed on-screen however the technicians administering the scans did not notice [2].

Similarly during an analysis of infusion pumps recalled by the FDA between 2005 and 2009, user errors were identified as one of the most common cause of the recalls [8]. It was found that on some devices the screen failed to make clear the units of measurement (pounds vs. kilograms) when entering patient data for calculating the dosage, leading to incorrect dosages being applied.

Although human error is an inevitable part of product usage, product designers have a responsibility to minimise the probability of human error occurring. To help developers achieve this goal usability practitioners have developed a series of heuristics and guidelines that have evolved from common issues that have been found with other devices. For example, Jacob Neilsen has developed a set of 10 general purpose heuristics that should help prevent usability errors. These heuristics were based on an analysis of 249 usability problems observed in 11 projects [19]. A number of heuris-

tics such as these have emerged for a range of domains including the World Wide Web and mobile applications.

Within the medical device domain ANSI/AAMI HE75:2009 [20] has been developed to provide a range of human factors design principles for medical devices across 25 sections ranging "from general considerations for human interface design to specific medical considerations such as surgical tools, mobile devices and connectors" [21].

In addition to the guidelines and design principles outlined above, the FDA and ISO recognise the importance of usability in a guidance document and international standard respectively. For medical devices sold within the US, the FDA have produced the Guidance document *Applying human factors and usability engineering to optimise medical device design* [6] which details a process for applying usability engineering during medical device development.

IEC have produced IEC 62366:2007 - *Medical Devices – Application of usability engineering to medical devices* [3] which is a FDA recognised consensus standard and is harmonized with the EU Medical Device Directive. IEC 62366 details the requirements for applying usability engineering to the design and development of medical devices. The standard focuses predominantly on risk management and risk control but also outlines some of the key requirements for performing usability engineering activities, such as user and context identification and analysis.

3 Software Process Improvement

There are many reasons why organisations undertake software process improvement evaluations. General purpose software process improvement frameworks, such as CMMI [5] and ISO/IEC 15504-5:2012 [4], can be used to help organisations to identify areas in which their software development processes can be improved.

In addition to this SPI models can be used to determine the state of a software development organisations practices for the purpose of supplier selection. In the late 1980s the US air force commissioned the development of a model to provide an objective evaluation of software subcontractors. This model, developed by the SEI at Carnegie Mellon University, became known as CMM and later CMMI.

3.1 Software Process Improvement Within the Medical Device Domain

The models described above have been developed for general purpose software process assessment and as such do not provide sufficient coverage to achieve medical device regulatory compliance [22]. To address this issue a medical device specific SPI framework, titled Medi SPICE, has been developed.

The objective of undertaking a Medi SPICE assessment is to determine the state of a medical device organisation's software processes and practices. This is in relation to the regulatory requirements of the industry and best practice with the goal of identifying areas for undertaking process improvement [22]. It can also be used as part of the supplier selection process when an organisation wishes to outsource or offshore

part or all of their medical device software development to a third party or remote division [23].

Medi SPICE is based upon the latest version of ISO/IEC 15504-5:2012 [4] and ISO/IEC 12207:2008 [24]. It is being developed in line with the requirements of ISO/IEC 15504-2:2003 [25] and contains a Process Reference Model (PRM) and Process Assessment Model (PAM). It also incorporates the requirements of the relevant medical device regulations, standards, technical reports and guidance documents.

The Medi SPICE PRM consists of 44 processes and 15 subprocesses which are fundamental to the development of regulatory compliant medical device software. Each process has a clearly defined purpose and outcomes that must be accomplished to achieve that purpose.

Medi SPICE also contains a PAM which is related to the PRM and forms the basis for collecting evidence that may be used to provide a rating of process capability. This is achieved by the provision of a two-dimensional view of process capability. In one dimension, it describes a set of process specific practices that allow the achievement of the process outcomes and purpose defined in the PRM; this is termed the process dimension. In the second dimension, the PAM describes capabilities that relate to the process capability levels and process attributes, this is termed the capability dimension [26].

3.2 Capability Maturity Models in Healthcare

Electronic health records pose serious risks to patient safety due to the volume of information they contain and the limited time available by medical practitioners to process these records. For this reason usability plays a major role in the presentation and organisation of medical health records and with healthcare organisations.

In 2011 the Healthcare Information and Management Systems Society (HIMSS), through the HIMSS usability task force [27] introduced a healthcare usability maturity model to allow "*health leaders and individuals to assess their levels of usability and then build to more advanced levels.*" The proposed model contains five different aspects of usability within the healthcare organisation; focus on users, management, process & infrastructure, resources and education.

The maturity model defines five levels at which an organisation can operate, summarised in the following table, taken from [27]:

Phase	Title	Description
1	Unrecognised	Lack of awareness of usability. No practices, policies or resources
2	Preliminary	Sporadic inclusion of usability. Very limited resources
3	Implemented	Recognized value of usability. Small team doing usability
4	Integrated	All benchmarks of usability implemented including, a dedicated user experience team
5	Strategic	Business benefits well understood, usability mandated, budget and people part of each year's budget, results used strategically throughout the organisation

Table 1. Healthcare usability Maturity Model Phases

4 Research Methodology

The aim of this work is to develop a software process improvement framework for medical device organisations' usability engineering processes. To meet this aim, the authors have developed a PRM incorporating existing usability engineering standards and guidance documents and will subsequently develop an ISO/IEC 15504-2 compliant PAM. The research methodology used is depicted in Fig. 2.

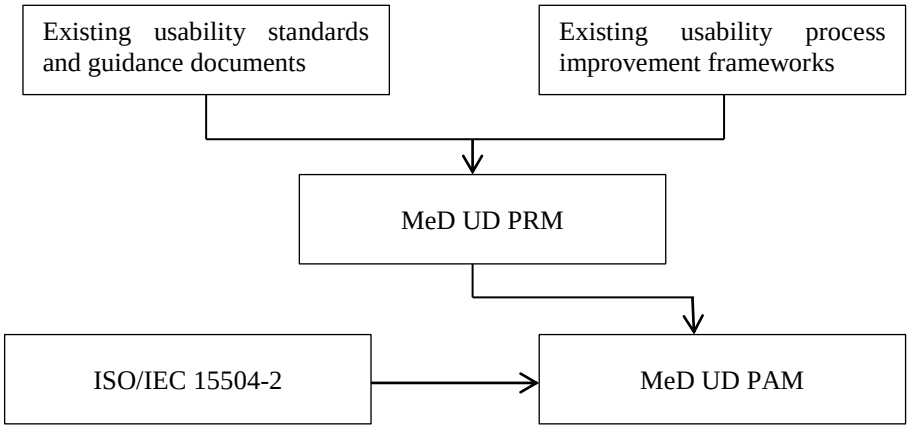

Fig.2. Research Methodology

It can be seen that the MeD UD PRM incorporates both existing usability standards and guidance documents and existing usability process improvement frameworks. Both the ISO and the FDA have produced significant guidance documents relating to the incorporation of human factors and usability engineering into the development of medical devices. An overview of these documents is provided in the following section.

4.1 Usability Standards and Guidance Documents

The IEC have produced the international standard IEC 62366:2007 – *Medical Devices – Application of usability engineering to Medical Devices* to help during the implementation of a usability engineering process. This standard specifies "a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to safety of a medical device" [3].

The standard places a strong focus on the identification and elimination of risks associated with the use of the medical device. As part of the usability engineering process, the standard highlights the importance of the identification of Hazards and Hazardous situations, a critical component of the risk management process.

In addition to this the standard in Section 5.7 Note 2, also recommends an iterative development cycle, specifying the need to perform usability validation throughout the design and development of the medical device.

As part of the usability engineering process, IEC 62366 specifies the need to perform usability verification, ensuring the user interface meets the requirements of the usability specification, and usability validation, ensuring that the primary operating functions can be accomplished through the user interface.

The standard not only requires usability to be incorporated into the medical device, it specifies that usability engineering should also be applied to the development of the User Manual and other supporting documentation as well as to training users in the use of the medical device and all material necessary to support this training.

While the standard does outline the requirements of the usability engineering process, it does not specify specific methods for achieving these requirements. This approach allows the organisation to select the most appropriate methods for the development of a particular medical device which meet the requirements of the standard.

For medical device manufacturers wishing to distribute their products within the United States of America, the FDA have produced the guidance document "*Applying human factors and usability engineering to optimise medical device design*" [6].

This document also emphasises the need for the incorporation of usability and human factors engineering throughout the entire development lifecycle. While IEC 62366 specifies that validation should be performed, the FDA guidance document provides guidance on how to perform validation, including the use of laboratory and clinical validation.

In addition the FDA guidance document outlines some of the methods that can be used to identify hazards and hazardous situations including, contextual analysis, interviews and focus groups, functional task analysis, Heuristic evaluation and Expert review.

4.2 Usability Process Improvement Frameworks

In addition to considering existing standards and guidance documents, during the course of this work a number of existing usability frameworks were considered. Trump [28] is an ISO/IEC 15504 compliant software process improvement method for human centred activities in the system lifecycle. The model is based on ISO 13407 *Human centred design processes for interactive systems* [29].

Trump has been developed to evaluate how well organisations are performing human centred design as part of system development and support projects. It can also be used to help organisations plan what human centred design activities to perform [28]. In addition to this the trump model can be used to help organisations evaluate their existing human-centred design activities.

Within this model there are 7 processes relating to the incorporation of human-centred activities into the software development process. The incorporated processes (descriptions taken directly from [28]) are:

- **Ensure Human Centred Design (HCD) content in system strategy: -** Establish and maintain focus on stakeholder and user issues in each part of the organisation which deal with system markets, concepts, development and support;
- **Plan and manage the HCD Process: -** Specify how the human centred activities fit into the whole system lifecycle process and the enterprise;

- **Specify stakeholders and Organisational requirements: -** Establish the requirements of the organisation and other interested parties for the system. This process takes full accountability of the needs, competencies and working environment of each relevant stakeholder in the system;
- **Understand and Specify the context of use: -** Identify, clarify and record the characteristics of the stakeholders, their tasks and the organisational and physical environment in which the system will operate;
- **Produce design solutions:-** Create potential design solutions by drawing on established state of the art practice, the experience and knowledge of the participants and the results of the context of use analysis
- **Evaluate designs against requirements: -** Collect feedback on the developing design. This feedback will be collected from end users and other representative sources
- **Introduce and operate the system: -** Establish the human-centred aspects of the support and implementation of the system.

An alternative to the Trump Assessment model is KESSU UD by Jokela [30]. Like Trump, KESSU UD is based on ISO 13407 but it also incorporates ISO/TR 18529 [31]. The model has been developed as an objective model for facilitating discussions with development staff during and after usability maturity assessments. The model has also been used as a basis for project planning and communicating the essence of usability to development managers and practitioners.

The KESSU UD model consists of seven processes described below;

- **Identification of user groups: -** During this processes the expected user groups are defined and categorised in a meaningful way. For example potential user groups on an infusion pump could be medical professionals, patients and home carers
- **Context of use analysis: -** The goal of this process is to define the potential user groups tasks, and the environment in which these tasks will be performed. For example a context of use for the aforementioned infusion pumps could be a noisy hospital ward in which a nurse could administer morphine to a patient.
- **User requirements determination: -** This process defines the usability and User Interface (UI) design requirements. The requirements shall be used to drive decision making during the design of the final system.
- **User task redesign: -** This process is used to design how users will carry out their task with the product under design.
- **Usability feedback: -** This process facilitates the qualitative evaluation of the product.
- **Usability verification: -** The usability verification process is used to measure the product under development against the usability and design requirements.
- **Interaction design: -** During this process the elements of the system that the user will interact with (Buttons, Radio Boxes, Text Displays, etc.) are designed. This also includes user documentation and training.

5 Med UD

The MeD UD framework, illustrated in Fig. 3 below, consists of 5 processes spanning the entire development process. The processes defined within the MeD UD framework are performed during the requirements gathering, implementation and testing phases of the software development life cycle. The following provides a high level overview of the processes of the MeD UD Process Reference Model:

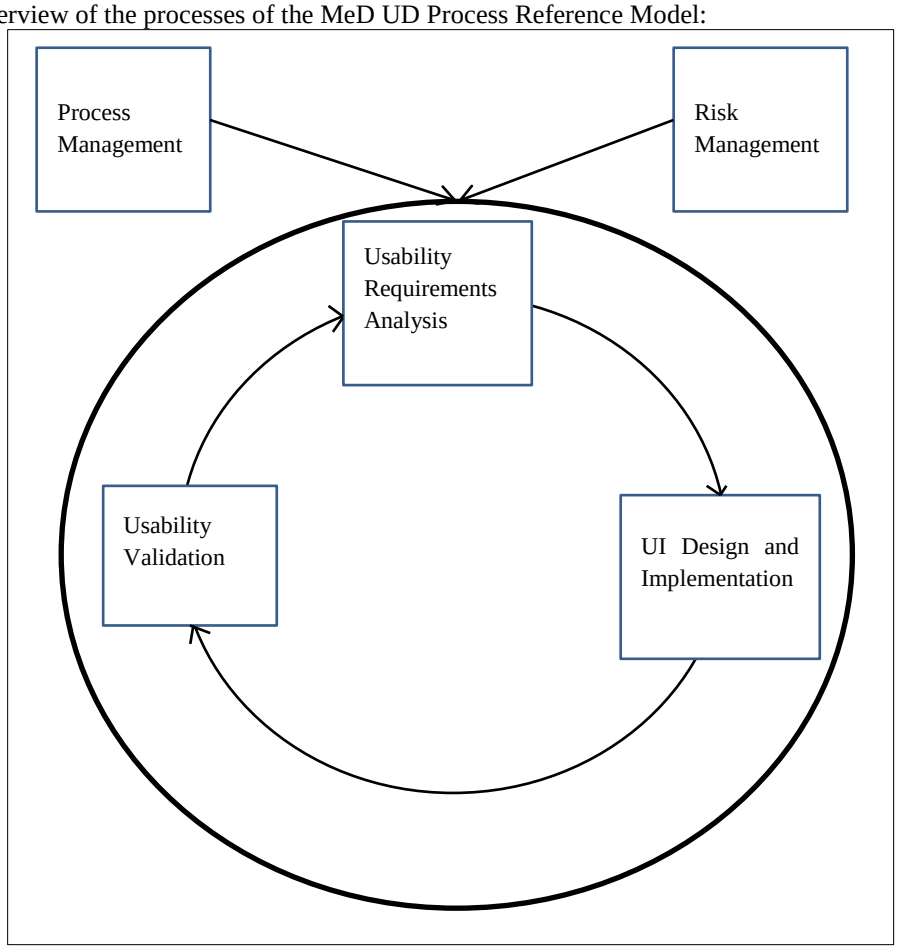

Fig.3. The MeD UD Framework

- **UD1 – Usability requirements analysis**: - The aim of this process is to define the usability requirements relating to the medical device. In defining these requirements the user, task, context and interaction are all considered. As part of the usability requirements all user groups are identified and analysed. During this analysis user profiles are created for each target user group and key characteristics, including users' level of training are considered.
  In addition to this all context(s) of use are identified and analysed. This analysis should include any environmental hazards that may be contained within the context

and their impact on the medical device and the interoperability of the medical device with other devices in the environment.
The usability requirements analysis should also identify and analyse the expected user interaction with the medical device. A significant aspect to this process is the identification of the primary operating and frequently used functions.

- **UD2 - Risk management:** - The second process is concerned with risk management. As user error during the use of the medical device carries significant risk, risk management activities relating to the use of the medical device should be carried out. This should be conducted in line with ISO 14971 (ISO, 2007), the risk management standard for the medical device domain, and focus on the risks associated with usability.

- **UD3 - User interface design and implementation**: - This process aims to mitigate against user risks through the development of the interface and supporting documentation. The interface should be developed in accordance with the usability specification. The supporting documentation should be developed in line with the user profiles so that it can be easily understood by the end user. The documentation should also include information relating to training in the use of the medical device.

- **UD4 - Usability validation**: - The Usability validation process aims to ensure that all usability requirements have been met. Validation is performed on a medical device representing the finished product that has been successfully verified against the usability specification.
  Prior to the validation, a validation plan is prepared. The validation should be performed in a realistic environment and should be sensitive enough to capture all use related problems whether or not the user is aware of such problems. The process covers both simulated use validation testing and clinical validation.
  - **Simulated use validation testing:** - During simulated use testing the participants should be representative of actual end users and the environment should be sufficient to enable generalisation to the anticipated actual use. The validation should include both subjective and objective measures.
  - **Clinical validation**: - The aim of clinical validation is to ensure adequate validation of the medical device within a clinical environment while ensuring the safety of participants and patients during the evaluation.

- **UD5 - Process management**: - This process ensures the appropriate management of the usability engineering process through process management. The process should be managed and documented in line with the requirements of the quality management system. To ensure adequate documentation all results of the usability process should be maintained in the usability engineering file.

6 Discussion

The proposed MeD UD assessment model is different from existing process assessment models for usability in a number of ways. Firstly, as the MeD UD assessment model has been developed based on guidelines from both the FDA and ISO it contains a strong emphasis on risk management in line with ISO 14971.

As part of the risk management process of MeD UD there is a requirement for organisations to identify the hazards relating to usability and the sequence or combination of events that can lead to a hazardous situation. This is not an explicit requirement in either the Trump or KESSU UD assessment models.

In addition to this the MeD UD also requires the specific documentation of the usability engineering process. This kind of documentation is mandated by the medical device regulations and as such is required in a usability assessment model for the medical device domain. In other domains such strict documentation is not required to market their products and is therefore not included within general usability assessment models to the same extent as in MeD UD.

The MeD UD assessment model has been developed to compliment Medi SPICE by focusing on the requirements for a usability engineering process. Should organisations wish to focus only on their usability processes they could undertake a MeD UD assessment rather than undertaking a full Medi SPICE assessment.

7 Future work

The next step of this work will be to validate the PRM. The PRM will be validated by experts from both academia and industry. As well as this it is intended to validate the model with experts within the software process improvement community.

Once the PRM has been validated, the PAM will be developed. In order to do this, the transformation method developed by Barafort et al. [32] will be utilised. This transformation method identifies key requirements for the PAM, in this case the PRM presented above and through a goal oriented approach produces a ISO/IEC 15504 compliant PAM.

In order to further develop and test the MeD UD framework, a MeD UD assessment will be performed within at least two medical device organisations. The goal of these assessments will be to identify the maturity of the organisation with regard to their software processes for usability and to assist them improve these processes. These assessments will also be researched and based on the results finding reports produced and submitted for expert review. The MeD UD PRM and PAM will be updated and amended based on feedback from these expert reviews.

8 Conclusions

The misapplication of a medical device can have serious or even fatal consequences on both the user and the patient. For this reason, human factors and usability engineering practices are used to minimise the risks associated with the use of a medical

device by ensuring that users can operate the device in a safe, effective and efficient manner.

A range of standards and guidance documents have emerged which can help developers implement these practices. These documents provide guidance on all aspects of development from the process to use to detailed guidelines on the most suitable components, and style of these components, to be used on a medical device.

In this paper the MeD UD framework is introduced. The MeD UD framework is a process improvement framework for improving human factors and usability engineering processes within the medical device domain. The framework consists of five processes across all aspects of the product development cycle.

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